Notice of Allowability	Application No.	Applicant(s)	
	09/655,074	NAKA ET AL.	
	Examiner	Art Unit	
	Lyle A. Alexander	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the 8/5/05 inteview summary*.

2. ☒ The allowed claim(s) is/are *18,28,9,11-17,30,38,39,41,44,75,50,61,64,66-72,74,76-87 renumbered as 1-39 respectively*.

3. ☒ The drawings filed on *08 June 2001* are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☒ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: *JAPAN 8-107310; JAPAN 8-236131*.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 4/26/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *8/5/05* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Mueller on 8/5/05.

9. A device as claimed in claim 28, wherein the opening has a shape enlarging toward the end.

11. A device as claimed in claim 28 , wherein the liquid flow resistance in the air vent passage is larger than the liquid flow resistance in the liquid pooling portion.

12. A device as claimed in claim 28, wherein the analytical section formed in the drawing channel serves as a reagent positioning section and a reagent reaction section.

13. A device as claimed in claim 28, wherein a reagent positioning section, a reagent reaction section and an analytical section are provided independently in certain positions in the drawing channel.

14. A device as claimed in claim 13, wherein a plurality of reagent positioning sections are provided in certain positions in the drawing channel.

15. A device as claimed in claim 28, wherein the suction pressure generator is a suction pressure generating chamber capable of changing its volume.

16. A device as claimed in claim 15, wherein a vent is formed in the suction pressure generating chamber.

17. A device as claimed in claim 28, wherein the suction pressure generator is a suction pressure generating tube.

18. A device for collecting a sample for analysis, comprising:

a main body dimensioned to be manipulated by hand, the device having at least one dimension selected from the group consisting of a length of 15-100 mm, a width of 20-50 mm, a width of 5-20 mm and a thickness of 1-5 mm;

a suction pressure generator;

a drawing channel formed in the main body in communication with the suction pressure generator, an opening in the main body being formed at the end of said drawing channel distal with respect to said suction pressure generator; and

an analytical section formed in said drawing channel between the suction generator and the opening, the analytical section communicating directly with the exterior of the device through the drawing channel; and

a pair of electrodes comprising a working electrode and a counter electrode provided in the analytical section,

wherein in use a sample is drawn into the main body through the opening by suction pressure developed by said suction pressure generator, and then the sample is transferred by the suction pressure through the drawing channel into the analytical section.

28. A device for collecting a sample for analysis, comprising:

a main body dimensioned to be manipulated by hand, the device having at least one dimension selected from the group consisting of a length of 15-100 mm, a width of 20-50 mm, a width of 5-20 mm and a thickness of 1-5 mm;

a suction pressure generator;

a drawing channel formed in the main body in communication with the suction pressure generator, an opening in the main body being formed at the end of said drawing channel distal with respect to said suction pressure generator;

an analytical section formed in said drawing channel between the suction generator and the opening, the analytical section communicating directly with the exterior of the device through the drawing channel; and

a liquid pooling portion formed between the opening and the drawing channel, and an air vent passage branching from a portion of the drawing channel between the liquid pooling portion and the analytical section, the end of the air vent passage opening to the outside,

wherein in use a sample is drawn into the main body through the opening by suction pressure developed by said suction pressure generator, and then the sample is transferred by the suction pressure through the drawing channel into the analytical section.

30. A device as claimed in claim 28, wherein the drawing channel is divided into a plurality of drawing channel members at a position between the opening and the suction pressure generator, each of the drawing channel members being provided with an analytical section and being in communication with the suction pressure generator.

38. A device as claimed in claim 28, wherein the drawing channel is divided into a plurality of drawing channel members at a position between the opening and the suction pressure generator.

39. A device as claimed in claim 28, wherein the suction pressure generator comprises a chamber formed in the main body in communication with the drawing channel.

41. A device as claimed in claim 28, wherein the device is designed to be discarded after a single use.

44. (Previously Presented) A device as claimed in claim 28, wherein a positive pressure can be generated to return a sample withdrawn from the analytical section to the analytical section.

50. A device for collecting a sample for analysis, comprising:

a main body dimensioned to be manipulated by hand;

a suction pressure generator comprising a chamber formed in the main body;

a drawing channel formed in the main body in communication with the chamber of the suction pressure generator, an opening in the main body being formed at the end of said drawing channel distal with respect to said suction pressure generator; and

a flexible cover on the main body, whereby changes in pressure in the chamber of the suction pressure generator are created by movement of the flexible cover,

the drawing channel being divided into a plurality of drawing channel members at a position between the opening and the suction pressure generator, each of the drawing channel members being provided with an analytical section and being in communication with the suction pressure generator,

each analytical section being formed in said drawing channel between the suction generator and the opening, each analytical section communicating directly with the exterior of the device through the drawing channel,

wherein in use a sample is drawn into the main body through the opening by suction pressure developed by said suction pressure generator, and then the sample is transferred by the suction pressure through the drawing channel into the analytical section.

61. A device as claimed in claim 50, wherein the device is designed to be discarded after a single use.

64. A device as claimed in claim 50, wherein a positive pressure can be generated to return a sample withdrawn from the analytical section to the analytical section.

66. A device as claimed in claim 50, wherein the opening has a shape enlarging toward the end.

67. A device as claimed in claim 50, wherein a liquid pooling portion is formed between the opening and the drawing channel, and an air vent passage branches from a portion

of the drawing channel between the liquid pooling portion and the analytical section, the end of the air vent passage opening to the outside.

68. A device as claimed in claim 67, wherein the liquid flow resistance in the air vent passage is larger than the liquid flow resistance in the liquid pooling portion.

69. A device as claimed in claim 50, wherein the analytical section formed in the drawing channel serves as a reagent positioning section and a reagent reaction section.

70. A device as claimed in claim 50, wherein a reagent positioning section, a reagent reaction section and an analytical section are provided independently in certain positions in the drawing channel.

71. A device as claimed in claim 70, wherein a plurality of reagent positioning sections are provided in certain positions in the drawing channel.

72. A device as claimed in claim 50, wherein a pair of electrodes comprising a working electrode and a counter electrode is provided in at least one analytical section.

74. A device as claimed in claim 50, wherein a concave portion with a cylindrical inner shape is formed in the main body as the chamber of the suction pressure generator and the flexible cover is disposed over the concave portion.

75. A device as claimed in claim 28, wherein the analytical section is wider than the drawing channel and the drawing channel extends from the analytical section to the suction pressure generator.

76. A device as claimed in claim 50, wherein the analytical section is wider than the drawing channel and the drawing channel extends from the analytical section to the suction pressure generator.

77. A device for collecting a sample for analysis, comprising:

a main body dimensioned to be manipulated by hand;

a suction pressure generator comprising a chamber formed in the main body;

a drawing channel formed in the main body in communication with the chamber of the suction pressure generator, an opening in the main body being formed at the end of said drawing channel distal with respect to said suction pressure generator;

a flexible cover on the main body, whereby changes in pressure in the chamber of the suction pressure generator are created by movement of the flexible cover;

an analytical section formed in said drawing channel between the suction generator and the opening, the analytical section communicating directly with the exterior of the device through the drawing channel; and

a pair of electrodes comprising a working electrode and a counter electrode provided in the analytical section,

wherein in use a sample is drawn into the main body through the opening by suction pressure developed by said suction pressure generator, and then the sample is transferred by the suction pressure through the drawing channel into the analytical section.

78. A device as claimed in claim 77, wherein the device is designed to be discarded after a single use.

79. A device as claimed in claim 77, wherein a positive pressure can be generated to return a sample withdrawn from the analytical section to the analytical section.

80. A device as claimed in claim 77, wherein the opening has a shape enlarging toward the end.

81. (New) A device as claimed in claim 77, wherein a liquid pooling portion is formed between the opening and the drawing channel, and an air vent passage branches from

a portion of the drawing channel between the liquid pooling portion and the analytical section, the end of the air vent passage opening to the outside.

82. A device as claimed in claim 81, wherein the liquid flow resistance in the air vent passage is larger than the liquid flow resistance in the liquid pooling portion.

83. A device as claimed in claim 77, wherein the analytical section formed in the drawing channel serves as a reagent positioning section and a reagent reaction section.

84. A device as claimed in claim 77, wherein a reagent positioning section, a reagent reaction section and an analytical section are provided independently in certain positions in the drawing channel.

85. A device as claimed in claim 84, wherein a plurality of reagent positioning sections are provided in certain positions in the drawing channel.

86. A device as claimed in claim 77, wherein a concave portion with a cylindrical inner shape is formed in the main body as the chamber of the suction pressure generator and the flexible cover is disposed over the concave portion.

87. A device as claimed in claim 77, wherein the analytical section is wider than the drawing channel and the drawing channel extends from the analytical section to the suction pressure generator.

The following is an examiner's statement of reasons for allowance: The cited prior art fails to teach or anticipate the claimed sample collection device comprising a

main body, a suction pressure generator, a drawing channel between the main body and suction pressure generator, an analytical section in the drawing channel, wherein the device further comprises an analytical section with a pair of electrodes or a liquid pooling portion formed between the opening and the drawing channel or a pluralilty of drawing channels at a position between the opening and the suction pressure generator where each channel has an analytical section.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander
Primary Examiner
Art Unit 1743

***